

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference CERT036PWO	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/EP2004/001029	International filing date (day/month/year) 04.02.2004	Priority date (day/month/year) 07.04.2003
International Patent Classification (IPC) or national classification and IPC		
Applicant CERVITECH, INC.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of <u>7</u> sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising: a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>8</u> sheets, as follows: <input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items: <input checked="" type="checkbox"/> Box No. I Basis of the report <input type="checkbox"/> Box No. II Priority <input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on (replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 3-14 as originally filed/furnished
- pages* 1, 2, 3a, 3b received by this Authority on 19.07.2004 with letter of 15.07.2004
- pages* _____ received by this Authority on _____
- ☒ the claims:
- nos. _____ as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* 1-10 received by this Authority on 19.07.2004 with letter of 15.07.2004
- nos.* _____ received by this Authority on _____
- ☒ the drawings:
- sheets 1/4-4/4 as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (specify): _____
- ☐ any table(s) related to sequence listing (specify): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (specify): _____
- ☐ any table(s) related to sequence listing (specify): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims		YES
	Claims	1-10	NO
Inventive step (IS)	Claims		YES
	Claims	1-10	NO
Industrial applicability (IA)	Claims	1-10	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

D1: US-B1-6 296 664 (MIDDLETON LANCE M)
2 October 2001 (2001-10-02)

D2: US-A-5 514 180 (HEGGENESS MICHAEL H ET AL)
7 May 1996 (1996-05-07)

D3: DE 44 23 826 A (ASAHI OPTICAL CO LTD)
12 January 1995 (1995-01-12)

D4: US-A-6 083 228 (MICHELSON GARY K)
4 July 2000 (2000-07-04)

D5: US-B1-6 517 580 (RAMADAN AYMEN ET AL)
11 February 2003 (2003-02-11).

2. The present application fails to satisfy the requirements of PCT Article 33(1) because the subject matter of claim 1 lacks novelty (PCT Article 33(2)).

Document D1 is considered to be the prior art closest to the subject matter of claim 1. Said document discloses (the references in brackets are to D1, see figures 6 and 8; column 5, lines 41-50):

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Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

an intervertebral joint prosthesis (100) for a predetermined intervertebral space in the cervical region of the spinal column, said space being delimited by the endplates of the adjacent vertebral bodies, the edge zones of the surfaces of said endplates having a high degree of curvature in a frontal plane that is laterally adjacent to a substantially flat central region; the central, less mineralised, region of one endplate surface (frontal section) being at a first distance from a mid-plane of the intervertebral space and the lateral, more strongly mineralised, lateral edge zone thereof being at a second distance from said mid-plane; the central surface region (134) of the prosthesis (same frontal section), which central surface region contacts the central region of the endplate surface, being at a third distance from the same mid-plane and the edge zones (108, 110) thereof, which edge zones contact the lateral edge zones of the endplate surface, being at a fourth distance from the same mid-plane, the third distance being greater than the fourth and the difference between the third and the fourth distances being greater than the difference between the first and the second distances (see also point 2.1 below).

2.1 As a result of the attempt to define the joint prosthesis in terms of features of the surrounding

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vertebrae, claim 1 lacks clarity (PCT Article 6). The curvature of individual endplates of the vertebrae and the size of the lateral edge zones vary from one vertebra to another and from one a person to another (see also D2, column 7, lines 21-25; figures). The same applies in respect of the geometry of the intervertebral spaces, which are dependent upon said curvature and size. There is no clear delimitation over the prior art. Claim 1 is drafted in such a way as to be prejudicial to novelty in respect of all intervertebral spaces that are geometrically related, as per said claim, to an existing intervertebral joint prosthesis with prosthesis surfaces (such as that known from D1). In the light of the aforementioned variation in individual vertebrae in different people, or indeed species, it is to be assumed that this applies in all cases. Consequently, the feature according to claim 1 is not restrictive in respect of the prostheses *per se*. For a surgeon, said claim is drafted such that, in effect, it indicates the choice of a suitable prosthesis for a specific intervertebral space, for example with regard to how the prosthesis should relate geometrically to this intervertebral space (the relationship between the different distances) but this relationship can also be obtained for intervertebral spaces (according to their respective geometry) using one of the prostheses according to D1, D2 or D3.

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Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
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- 2.2 In addition to D1, documents D2 (in particular, see also column 5, lines 16-33) and D3 disclose all the features of claim 1 (see above).
- 2.3 Independent claim 10 lacks novelty (PCT Article 33(2)) since an instrument with a rasp that reflects the shape of the prosthesis was disclosed in D4 (see claim 35; figures 21 to 23).
3. Dependent claims 2-8 do not contain any features which, in combination with the features of any claim to which they refer back, meet the PCT requirements for novelty and inventive step. The reasons are as follows:
- 3.1 Claims 2, 3 and 5-7: the technical features of these claims were disclosed in D1 (see figures 6 and 8). The observations made in respect of claim 1, with regard to clarity, apply similarly to claim 2.
- 3.2 Claim 4: a toothed central region has already been disclosed in D5 (see figures 1, 4 and 5).
- 3.3 Claim 8: since the dorsal and ventral halves of an intervertebral space are formed differently in each individual, and thus differ in shape from one individual to another, the remarks made in point 2.1 apply similarly with regard to claim 8 (see also D2, column 3, lines 11-21).

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3.4 Claim 9: the remarks made under points 2.1 and 3.3 apply similarly with regard to claim 9. A prosthesis cover plate with dorsolaterally slanted surfaces as per claim 9 has already been disclosed in D2 (see in particular column 5, lines 34-42; figure 2).